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EXAMINER

MEHTA, PARIKHA SOLANKI

ART UNIT	PAPER NUMBER
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3737

NOTIFICATION DATE	DELIVERY MODE
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05/23/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/552,819	Applicant(s) GLEICH ET AL.	
	Examiner PARIKHA S. MEHTA	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/27/11</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3737

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraus, Jr (US Patent No. 6,470,220), hereinafter Kraus, Jr. ('220), in view of Klaveness (US Patent No. 5,628,983), hereinafter Klaveness ('983).

Regarding claims 1 and 8, Kraus, Jr. ('220) teaches a method of generating a magnetic field having a "relatively uniform" field strength, wherein "relatively uniform" is interpreted as meaning "not perfectly uniform", i.e. the field must implicitly have a first sub-area of lower field strength and a second sub-area of higher strength (col. 13 lines 20-22). Kraus, Jr. ('220) goes on to teach changing the spatial position of the field, which includes the two sub-areas, so that a magnetization of administered particles changes locally, acquiring signals depending on such magnetization, and evaluating the acquired signals to obtain information about the change in spatial distribution of the particles (col. 13 lines 9-32). The particles of Kraus, Jr. ('220) are considered to be at least partly anisotropic in that their rotation varies when measured in different directions.

Kraus, Jr. ('220) does not teach the magnetic particles as comprising a superparamagnetic material. Kraus, Jr. ('220) does suggest the use of magnetic micro- or nano-particles (col. 4 lines 15-16). In the same field of endeavor, Klaveness ('983) teaches that superparamagnetic particles are effective

Art Unit: 3737

contrast agents for SQUID imaging (col. 2 lines 11-23). It would have been obvious to a skilled artisan to have used superparamagnetic particles as the micro- or nano-particles of Kraus, Jr. ('220) and thereby yield the claimed invention, in view of the teachings of Klaveness ('983).

Regarding claim 7, Kraus, Jr. ('220) teaches applying the reference method to an examination area including mammary glands of an organism (col. 3 lines 33-44, teaching of application for breast cancer).

Regarding claim 5, although Kraus, Jr. ('220) does not expressly teach applying the reference method to examination of a material having boreholes or a material made of plastic or ceramic, or a material comprising a polymer, it is well known in the art that these are features of artificial tissue phantoms commonly used to test imaging methods. Accordingly, it would have been obvious to a skilled artisan to have performed the method of Kraus, Jr. ('220) on an examination area including a tissue phantom comprising boreholes, plastic or ceramic materials, in order to test the efficacy of the reference imaging method prior to applying it to a living subject.

Regarding claim 6, Kraus, Jr. ('220) teaches rotating the field through multiple positions, which constitutes repeating steps b) through d) as claimed (col. 13 lines 33-62).

4. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kraus, Jr. ('220) and Klaveness ('983) as previously applied to claim 1, further in view of Ivkov (US PG Pubs. No. 2006/0142749). Kraus, Jr. ('220) and Klaveness ('983) do not expressly teach the particles to be mono-domain particles which are magnetically reversed through Brownian or Neel rotation. In the same problem solving area, Ivkov ('749) teaches a method of examining a patient including the step of administering monodomain magnetic particles configured to be reversed via Neel rotation (§§ 15, 16, 22, 27, 63-64). It would have been obvious to a skilled artisan to have tried to use the particles of Ivkov ('749) with the method of Kraus ('220) and Klaveness ('983) and to thereby yield the claimed invention, as both references are directed towards tracking and treating tumors (*KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

5. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kraus, Jr. ('220) and Klaveness ('983) as previously applied to claim 1, further in view of Rand (US PG Pubs. No. 2005/0066961), hereinafter Rand ('961). Kraus, Jr. ('220) and Klaveness ('983) do not teach the particles as being hard or soft magnetic multi-domain particles. In the same problem solving area, Rand ('961) teaches a method of magnetic imaging of an examination area including the step of administering soft,

Art Unit: 3737

multi-domain magnetic contrast particles (§ 10). It would have been obvious to a skilled artisan to have tried to use the particles of Rand ('610) in the method of Kraus, Jr. ('220) and Klaveness ('983) and to thereby yield the claimed invention, as both references are directed towards tracking and treating tumors (*KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

6. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraus, Jr. ('220) and Klaveness ('983) as previously applied to claim 1, further in view of Frei et al (US Patent No. 3,592,185), hereinafter Frei ('185). Kraus, Jr. ('220) and Klaveness ('983) do not expressly teach the magnetic particles as comprising hard magnetic particles such as Al-Ni, Al-Ni-Co, Fe-Co-V, or barium ferrite. In the same field of endeavor of magnetic contrast imaging, Frei ('185) teaches use of barium ferrite as a particle contrast agent. It would have been obvious to one of ordinary skill in the art at the time of invention to have performed the method of Kraus, Jr. ('220) and Klaveness ('983) using barium ferrite as taught by Frei ('185) for the magnetic particles, as such a combination of known prior art steps to yield predictable results has previously been held as obvious and unpatentable (*KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or

Art Unit: 3737

claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1 and 5-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11, 39 and 40 of copending Application No. 10/552,818.

Regarding claims 1 and 8-12, although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims merely recite the additional limitation of the magnetic particle being a superparamagnetic particle. Applicant admits that the use of superparamagnetic particles was known in the art at the time of invention for increasing contrast (Specification ¶ 3). Furthermore, Applicant places no particular criticality on the use of superparamagnetic particles in the claimed invention. Accordingly, it would have been obvious to a skilled artisan to have tried to use superparamagnetic particles to achieve the invention of the '820 application (*KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

Regarding claims 5 and 7, the limitations towards performing the method on a phantom are not a patentable advance over the conflicting claims for reasons similar to those discussed above under 35 U.S.C. 103(a).

Regarding claim 6, it would have been obvious to a skilled artisan to have repeated steps b-d in order to obtain additional information about the spatial distribution and/or movement of the particles within the examination area.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1 and 5-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 20, 21 and 25 of copending Application No. 10/552,820.

Regarding claims 1 and 8-12, although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims merely recite the additional limitation of the magnetic particle being a superparamagnetic particle. Applicant admits that the use of superparamagnetic particles was known in the art at the time of invention for increasing contrast (Specification ¶ 3). Furthermore, Applicant places no particular criticality on the use of superparamagnetic particles in the claimed invention. Accordingly, it would have been obvious to a

Art Unit: 3737

skilled artisan to have tried to use superparamagnetic particles to achieve the invention of the '820 application (*KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

Regarding claims 5 and 7, the limitations towards performing the method on a phantom are not a patentable advance over the conflicting claims for reasons similar to those discussed above under 35 U.S.C. 103(a).

Regarding claim 6, it would have been obvious to a skilled artisan to have repeated steps b-d in order to obtain additional information about the spatial distribution and/or movement of the particles within the examination area.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1 and 5-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10 and 11 of copending Application No. 10/552,806.

Regarding claims 1 and 8-12, although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims merely recite the additional limitation of the magnetic particle being a superparamagnetic particle. Applicant admits that the use of superparamagnetic particles was known in the art at the time of invention for increasing contrast (Specification ¶ 3). Furthermore, Applicant places no particular criticality on the use of superparamagnetic particles in the claimed invention. Accordingly, it would have been obvious to a skilled artisan to have tried to use superparamagnetic particles to achieve the invention of the '820 application (*KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

Regarding claims 5 and 7, the limitations towards performing the method on a phantom are not a patentable advance over the conflicting claims for reasons similar to those discussed above under 35 U.S.C. 103(a).

Regarding claim 6, it would have been obvious to a skilled artisan to have repeated steps b-d in order to obtain additional information about the spatial distribution and/or movement of the particles within the examination area.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 1 and 5-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of US Patent No. 7,619,408.

Art Unit: 3737

Regarding claims 1 and 8-12, although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are merely commensurate in scope with or broader than the conflicting claims, with the exception of the additional present limitation of the magnetic particle being a superparamagnetic particle. Applicant admits that the use of superparamagnetic particles was known in the art at the time of invention for increasing contrast (Specification ¶ 3). Furthermore, Applicant places no particular criticality on the use of superparamagnetic particles in the claimed invention. Accordingly, it would have been obvious to a skilled artisan to have tried to use superparamagnetic particles to achieve the invention of the '820 application (*KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

Regarding claims 5 and 7, the limitations towards performing the method on a phantom are not a patentable advance over the conflicting claims for reasons similar to those discussed above under 35 U.S.C. 103(a).

Regarding claim 6, it would have been obvious to a skilled artisan to have repeated steps b-d in order to obtain additional information about the spatial distribution and/or movement of the particles within the examination area.

12. Claims 1 and 5-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of US Patent No. 7,778,681.

Regarding claims 1 and 8-12, although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims merely recite the additional limitation of the magnetic particle being a superparamagnetic particle. Applicant admits that the use of superparamagnetic particles was known in the art at the time of invention for increasing contrast (Specification ¶ 3). Furthermore, Applicant places no particular criticality on the use of superparamagnetic particles in the claimed invention. Accordingly, it would have been obvious to a skilled artisan to have tried to use superparamagnetic particles to achieve the invention of the '820 application (*KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

Regarding claims 5 and 7, the limitations towards performing the method on a phantom are not a patentable advance over the conflicting claims for reasons similar to those discussed above under 35 U.S.C. 103(a).

Regarding claim 6, it would have been obvious to a skilled artisan to have repeated steps b-d in order to obtain additional information about the spatial distribution and/or movement of the particles within the examination area.

Art Unit: 3737

13. Claims 1 and 5-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of US Patent No. 7,747,304.

Regarding claims 1 and 8-12, although the conflicting claims are not identical, they are not patentably distinct from each other because they merely recite obvious variations and groupings of the same method steps.

Regarding claims 5 and 7, the limitations towards performing the method on a phantom are not a patentable advance over the conflicting claims for reasons similar to those discussed above under 35 U.S.C. 103(a).

Regarding claim 6, it would have been obvious to a skilled artisan to have repeated steps b-d in order to obtain additional information about the spatial distribution and/or movement of the particles within the examination area.

Response to Amendments and Arguments

14. Applicant's amendments of 27 Dec 2010 are sufficient to overcome the previous objections to the claims and specification, as well as the rejections under 35 U.S.C. 112, which are hereby vacated.

15. Applicant's arguments of 27 Dec 2010 with respect to claims 1 and 5-12 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3737

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PARIKHA S. MEHTA whose telephone number is (571)272-3248. The examiner can normally be reached on M-F, 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Parikha S Mehta/
Examiner, Art Unit 3737